



This document is scheduled to be published in the Federal Register on 12/01/2011 and available online at <http://federalregister.gov/a/2011-30795>, and on FDsys.gov

Billing Code 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities:
Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS. ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Use of Deliberative Methods to Enhance Public Engagement in the Agency for Healthcare Research and Quality's (AHRQ's) Effective Healthcare (EHC) Program and Comparative Effectiveness Research (CER) Enterprise." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by [insert date 60 days after date of publication].

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at dorislefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Use of Deliberative Methods to Enhance Public Engagement in the Agency for Healthcare Research and Quality's (AHRQ's) Effective Healthcare (EHC) Program and Comparative Effectiveness Research (CER) Enterprise

With this project, AHRQ seeks evidence on the feasibility and usefulness of public deliberation as an approach to obtaining public input on questions related to the conduct and use of comparative effectiveness research (CER). Although stakeholder engagement has been central to the Effective Healthcare (EHC) program to date, public input has not traditionally been used to inform and guide broad strategies related to the use of evidence to inform decisions. This study would provide a research base to address this gap. This project closely ties to AHRQ's efforts to improve the rigor of methods, as it will generate methodological evidence through a randomized controlled experiment comparing five distinct methods of public deliberation to find the most effective approaches for involving the general public, including members of AHRQ's priority populations, in questions related to the research enterprise. Public deliberation is a strategy for engaging lay people in informing decisions when these decisions require consideration of values and ethics in addition to scientific evidence. It includes three core elements:

- 1) Convening a group of people (either in person or via online technologies to connect people in remote locations),

- 2) Educating the participants on the relevant issue(s) through dissemination of educational materials and/or the use of content experts, and
- 3) Having the participants engage in a reason-based discussion, or deliberation, on all sides of the issue(s).

AHRQ wishes to study the effectiveness of public deliberation, because it offers the opportunity to obtain public input on complex topics in an environment that encourages participants to educate themselves about the topic and discuss it in a thoughtful, respectful manner. Information about the topic is intentionally neutral and respectful of the full range of underlying values and experience with health care issues in the population. This approach is designed to improve upon the sometimes superficial or "top of mind" responses that are often provided by public opinion surveys. AHRQ views public deliberation as a potential source of higher quality public input on issues fundamental to the Agency's mission, such as the best and most effective ways to use comparative effectiveness research, than has heretofore been available.

Several distinct deliberative methods have been developed and used previously. They share the three core elements of public deliberation, but differ on key features of implementation such as duration, whether they take place in-person or online, and the use of content experts. Although there is considerable theoretical and case study literature endorsing the value of public deliberation, there has been little empirical research about its effectiveness and even less about the comparative merits of different deliberative methods (Community Forum Deliberative Methods Literature Review, 2010).

The objectives of this study are to:

1. Obtain informed and deliberated input from lay people on important questions underlying AHRQ's research program; and
2. Expand the evidence base for the use of public deliberation methods for exploring issues relevant to health care research by comparing the outcomes of five distinct deliberative methods to a control condition and to each other.

This study is being conducted by AHRQ through its contractor, the American Institutes of Research (AIR), pursuant to AHRQ's statutory authority to (1) promote health care quality improvement by conducting and supporting both research that develops and presents scientific evidence regarding all aspects of health care and the synthesis and dissemination of available scientific evidence for use by policymakers, among others, and (2) conduct and support research, provide technical assistance, and disseminate information on healthcare and on systems for the delivery of such care. See 42 U.S.C. 299(b)(1)(A), (D), (F), and (G); 42 U.S.C. 299(b)(2); 42 U.S.C. 299a(a)(1) – (4).

Method of Collection

To achieve the objectives of this study the following activities and data collections will be implemented:

- 1) Participant recruitment - A short screening questionnaire, including a brief overview of the study, will be used to recruit persons for the study.
- 2) Educational Materials - Educational materials are designed to inform participants about the topics that are being deliberated and will be provided to all 1,685 participants recruited before the implementation of any of the methods, but after the administration of the Knowledge and Attitudes Pre-test Survey (described below). Additional content provided during the deliberative

method sessions includes an overview of the study and the background materials needed by participants to competently deliberate the issues. For two methods (ODP and IDP; see below) educational materials to be used during the sessions will be sent to participants before the sessions (but after administration of the pre-test).

3) Deliberative Discussion Groups and Control Group - The purpose of the discussion groups is to obtain informed and deliberated input from lay people on an important set of issues underlying health care research. Participants will be randomly assigned to one of the five deliberative methods or a control condition. The five methods were selected because they have been previously implemented and vary on key features that may affect the scalability and effectiveness of the methods, including: duration (from two hours to three days), mode of implementation (online versus in person), role of content experts, and time between sessions allowing participants to seek additional information on the issues and communicate informally with other participants. The subject of the deliberations is the use of research evidence in healthcare decision-making. This deliberative topic encompasses several themes or "variations" that will be elaborated in the deliberations:

1. Use of evidence to encourage better healthcare: Is evidence useful (or, what kind of evidence is useful) to a physician and a patient who are considering a test or treatment that has been found to be ineffective, less effective than another, riskier than another, or for which effectiveness has not been demonstrated?

2. Use of evidence to encourage better value: Is evidence useful (or, what kind of evidence is useful) to a physician and a patient who are considering a test or treatment that is effective even though an equally effective but less expensive alternative is available?.

3. Decision-making when evidence shows more complex trade-offs: Is evidence useful (or, what kind of evidence is useful) in treatment decisions that involve the balancing of effectiveness, risk, and value?

The issues involved in each variation will be discussed in the context of specific comparative effectiveness research (CER) examples. These "vignettes" illustrate the issues and elicit participants' input on the issues and the values employed by participants in the deliberations.

4) Knowledge and Attitudes Pre-test Survey – This survey will measure knowledge of and attitudes about the health issues discussed in the deliberations. It will be administered to deliberation participants and controls before educational materials are sent or the methods are implemented.

As described, study participants will be provided with educational materials related to the deliberative topic. In order to assess whether or not participants were sufficiently informed on the topics addressed in the materials, the Knowledge and Attitudes Survey contains items assessing knowledge of medical research and medical evidence, of comparative effectiveness research, and of healthcare costs. The attitudinal questions refer to the use of medical evidence in healthcare decision making. They include attitudes about health care decision-making when research findings can provide no support for, or conflict with patient and doctor preferences for particular treatments.

The questionnaire will also gather demographic and other information necessary to characterize the study sample, test the success of the randomization, and define population subgroups for which variation in outcomes will be examined. The demographic variables also will be used to control for participant and group

characteristics that may influence the outcomes. Even though the design involves randomization, and these characteristics should be balanced across groups, including them in the statistical models guards against inadequate results from randomization.

The variables to be measured in the Knowledge and Attitudes Pre-test Survey include:

- Sociodemographic characteristics: gender, age, marital status, education, employment status, household income, race/ethnicity, priority population, languages spoken (in addition to English)
- General health status
- Recent experience with the healthcare system (e.g., seeing a healthcare provider more than three times for the same condition in the last 12 months)
- Health insurance coverage
- Health information-seeking behavior (e.g., the extent to which people seek healthcare information or rely on their doctors to provide information)

5) Knowledge and Attitudes Post-test Survey – This survey will measure knowledge of and attitudes about the issues discussed in the deliberations after the deliberations take place. It will be administered to deliberation participants and controls within one week following conclusion of the deliberative methods and will include the same knowledge and attitude questions as the pre-test questionnaire.

6) Deliberative Experience Survey –As described above, the five deliberative methods being tested vary in terms of duration, mode, use of educational

materials, and time between deliberative sessions. A one-time survey will be administered to participants in the deliberative methods after implementation of the experimental conditions to compare deliberative methods to each other. Levels of discourse quality and implementation quality achieved will be assessed. Using multi-item scales, the survey will measure the following:

Discourse quality

- Equal participation in the discussions
- Respect for others' opinions and tolerance of differing perspectives
- Appreciation of perspectives other than their own
- Reasoned justification of ideas: sharing the reasoning or rationale for positions, opinions, beliefs, or preferences

Implementation quality

- Quality of group facilitation
- Quality of the educational materials provided
- Quality of the experts
- Transparency of the process and use of the results
- Participants' perceived value of method
- Participants' view of the influence the results will have on programs

In sum, information collection in this study will entail qualitative transcript review and quantitative surveys. This information will be used to describe and summarize the input obtained from the participants in the deliberative groups concerning the use of evidence, presenting the findings in reports for AHRQ and the public.

The information from the surveys also will be used to expand the evidence base for public deliberation. The experiment is designed to: (1) compare the

effectiveness of the five deliberative methods to the control condition and to each other, (2) compare the quality of the discourse achieved by the deliberative methods to each other, (3) assess the quality of implementation of the five methods, and (4) test for variation in effectiveness and discourse quality by features of the deliberations and for population subgroups defined by sociodemographic characteristics of the participants.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden associated with the respondents' time to participate in this research. The total annualized burden hours are estimated to be 11,647 hours. The burden estimate comprises the following activities:

Participant Recruitment – The screening questionnaire and recruitment letter and materials will be sent to 1,685 participants. We estimate that it will take 15 minutes to complete the questionnaire and review the recruitment letter and materials.

Educational materials -- Educational materials will be provided to all 1,685 participants recruited before the implementation of any of the methods. We estimate that it will take up to 1 hour to review the materials.

Short Citizens' Deliberation (SCD): This method will be tested with 192 participants (12 groups). Participants will attend a single, 2-hour in-person meeting.

Online Deliberative Polling® (ODP): This method will be tested with 288 participants (24 groups) and will consist of 4 online sessions over the course of 4 weeks; in total, this method will take about 5 hours per person.

In-Person Deliberative Polling® (IDP): This method will be tested with 288 participants (16 groups); participants will attend a single in-person meeting, lasting a full day.

Citizens' Panel (CP): This method will be tested with 96 participants (4 groups); participants will attend a 3-day, in-person meeting.

Interrupted Deliberation (ID): This method will be tested with 192 participants (12 groups). Participants will attend 2 in-person meetings, lasting 3 hours each, a week apart. Between meetings, participants will be asked to access an online platform. In total, this method will take about 6 hours per person.

Knowledge and Attitudes Pre-test Survey: This survey will be administered to 1,685 participants and will take an estimated 30 minutes to complete.

Knowledge and Attitudes Post-test Survey: This survey will be administered to 1,685 participants and will take an estimated 20 minutes to complete.

Deliberative Experience Survey: This survey will be administered to 1,056 deliberative methods participants at the conclusion of the deliberative method. It will take about 15 minutes to complete.

Exhibit 1. Estimated annualized burden hours

Form Name/Deliberative Method	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Recruitment and Consent Materials	1685	1	15/60	421
Short Citizens' Deliberation (SCD)	192	1	2	384
Online Deliberative Polling® (ODP)	288	1	5	1440
In-Person Deliberative				

Polling® (IDP)	288	1	9	2592
Citizens' Panel	96	1	24	2304
Interrupted Deliberation (ID)	192	1	6	1152
Educational Materials	1685	1	1	1685
Knowledge and Attitudes Pretest Survey	1685	1	30/60	843
Knowledge and Attitudes Posttest Survey	1685	1	20/60	562
Deliberative Experience Survey	1056	1	15/60	264
Total	8852	N/A	N/A	11647

Exhibit 2. Estimated annualized cost burden

Form Name/Deliberative Method	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Recruitment and Consent Materials	1685	421	\$21.35	\$8,988
Short Citizens' Deliberation (SCD)	192	384	\$21.35	\$8,198
Online Deliberative Polling® (ODP)	288	1440	\$21.35	\$30,744
In-Person Deliberative Polling® (IDP)	288	2592	\$21.35	\$55,339
Citizens' Panel	96	2304	\$21.35	\$49,190
Interrupted Deliberation (ID)	192	1152	\$21.35	\$24,595
Educational Materials	1685	1685	\$21.35	\$35,975
Knowledge and Attitudes Pretest Survey	1685	843	\$21.35	\$17,998
Knowledge and Attitudes Post-test Survey	1685	562	\$21.35	\$11,999
Deliberative Experience Survey	1056	264	\$21.35	\$5,636
Total	8852	N/A	N/A	\$248,662

*Based upon the mean of the wages for 00-000 All Occupations (\$21.35), May 2010 National Occupational Employment and Wage Estimates. United States, "U.S. Department of Labor, Bureau of Labor Statistics."
http://www.bls.gov/oes/current/oes_nat.htm#00-0000

Estimated Annual Costs to the Federal Government

Exhibit 3 below breaks down the costs related to this study. These are the costs associated with the portion of the contract awarded to AIR to conduct the experiment. Since the implementation and evaluation periods will span 24 months, the costs have been annualized by taking the total cost and dividing by 2.

Exhibit 3. Estimated Annualized Cost to the Federal Government

Cost Component	Total Cost	Annualized Cost
Project Management	\$60,106	\$30,053
Technical Expert Panel	\$117,793	\$58,896
Technology Tools	\$177,580	\$88,790
Develop Educational Materials	\$368,624	\$184,312
Evaluation Plan	\$214,566	\$107,283
Implement Methods	\$1,624,169	\$812,085
Conceptual Framework	\$50,195	\$25,098
Data Processing and Analysis	\$566,846	\$283,423
Reporting	\$135,693	\$67,847
Overhead	\$1,281,340	\$640,670
Total	\$4,596,914	\$2,298,457

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of

AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 16, 2011

Carolyn Clancy, M.D.
Director

[FR Doc. 2011-30795 Filed 11/30/2011 at 8:45 am; Publication Date: 12/01/2011]